



**ENVIRONMENTAL PROTECTION AGENCY**

6560-50

**[EPA-HQ-OPPT-2011-0699; FRL-9520-3]**

**Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act, this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: **Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment**; EPA ICR No. 1031.10, OMB No. 2070-0017. The ICR, which is abstracted below, describes the nature of the information collection activity and its expected burden and costs.

**DATES:** Additional comments may be submitted on or before [insert date 30 days after publication in the Federal Register].

**ADDRESSES:** Submit your comments, referencing docket ID Number EPA-HQ-OPPT-2011-0699 to (1) EPA online using [www.regulations.gov](http://www.regulations.gov) (our preferred method), by email to [oppt.ncic@epa.gov](mailto:oppt.ncic@epa.gov) or by mail to: Document Control Office (DCO), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, Mail Code: 7407T, 1200 Pennsylvania Ave., NW, Washington, D.C. 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Pamela Myrick, Acting Director,

Environmental Assistance Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, Mail code: 7408-M, 1200 Pennsylvania Ave., N.W., Washington, DC 20460; telephone number: 202-554-1404; e-mail address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:**

EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On October 25, 2011 (76 FR 66061), EPA sought comments on this renewal pursuant to 5 CFR 1320.8(d). EPA received no comments during the comment period. Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA EPA-HQ-OPPT-2011-0699, which is available for online viewing at <http://www.regulations.gov>, or in person inspection at the OPPT Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202-566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is 202-566-0280. Use [www.regulations.gov](http://www.regulations.gov) to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select “search,” then key in the docket ID number identified above.

EPA’s policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in [www.regulations.gov](http://www.regulations.gov) as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. When EPA identifies

a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in [www.regulations.gov](http://www.regulations.gov). The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in [www.regulations.gov](http://www.regulations.gov). For further information about the electronic docket, go to [www.regulations.gov](http://www.regulations.gov).

**Title:** Recordkeeping and Reporting Requirements for Allegations of Significant Adverse Reactions to Human Health or the Environment.

**ICR Status:** This is a request to renew an existing approved collection. This ICR is scheduled to expire on August 31, 2012. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

**Abstract:** TSCA section 8(c) requires companies that manufacture, process, or distribute chemicals to maintain records of significant adverse reactions to health or the environment alleged to have been caused by such chemicals. Since section 8(c) includes no automatic reporting provision, EPA can obtain and use the information contained in company files only by inspecting those files or requiring reporting of records that relate to specific substances of concern. Therefore, under certain conditions, and using the provisions found in 40 CFR part 717, EPA may require companies to report such allegations to the Agency.

EPA uses such information on a case-specific basis to corroborate suspected adverse health or environmental effects of chemicals already under review by EPA. The information is also useful to identify trends of adverse effects across the industry that may not be apparent to

any one chemical company. This ICR addresses the information reporting and recordkeeping requirements found in 40 CFR part 717.

Responses to the collection of information are mandatory (see 40 CFR part 717). Respondents may claim all or part of a notice as CBI. EPA will disclose information that is covered by a CBI claim only to the extent permitted by, and in accordance with, the procedures in 40 CFR part 2.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the Federal Register, are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

**Burden Statement:** The annual public reporting and recordkeeping burden for this collection of information is estimated to range between approximately 1 minute and 8 hours per response, depending upon the type(s) of activity that a respondent must complete. Burden is defined in 5 CFR 1320.3(b).

*Respondents/Affected Entities:* Entities potentially affected by this action are companies that manufacture, process, import, or distribute in commerce chemical substances or mixtures.

*Frequency of Collection:* On occasion.

*Estimated No. of Respondents:* 13,951.

*Estimated Total Annual Burden on Respondents:* 26,978 hours.

*Estimated Total Annual Costs:* \$1,797,800.

*Changes in Burden Estimates:* This request reflects an increase of 3,442 hours (from 23,536 hours to 26,978 hours) in the total estimated respondent burden from that currently in the

OMB inventory. This increase reflects EPA's estimate of a greater number of potential respondents affected by the reporting requirement. The Supporting Statement provides details about the change in burden estimate. The change is an adjustment.

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John Moses,  
Director,  
Collection Strategies Division

[FR Doc. 2012-17485 Filed 07/17/2012 at 8:45 am; Publication Date: 07/18/2012]